

## PATENT COOPERATION TREATY

Rec'd PCT/PTO 20 SEP 2005

10/549617

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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London NW11 8DS  
GRANDE BRETAGNENOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing  
(day/month/year)

22.07.2005

Applicant's or agent's file reference  
0300091

## IMPORTANT NOTIFICATION

International application No.  
PCT/GB2004/001707International filing date (day/month/year)  
21.04.2004Priority date (day/month/year)  
25.04.2003Applicant  
SMITHS GROUP PLC et Al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

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preliminary examining authority:European Patent Office - P.B. 5818 Patentlaan 2  
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# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0300091	<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/GB2004/001707	International filing date (day/month/year) 21.04.2004	Priority date (day/month/year) 25.04.2003	
International Patent Classification (IPC) or national classification and IPC A61M16/04			
Applicant SMITHS GROUP PLC et Al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 9 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau a total of 2 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand  28.09.2004		Date of completion of this report  22.07.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016		Authorized Officer Zeinstra, H Telephone No. +31 70 340-2824 	

# INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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JC05 Rec'd PCT/PTO 20 SEP 2005

## Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - ☐ international search (under Rules 12.3 and 23.1(b))
    - ☐ publication of the international application (under Rule 12.4)
    - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

### Description, Pages

1-7 as originally filed

### Claims, Numbers

1-10 received on 28.09.2004 with letter of 28.09.2004

### Drawings, Sheets

1/2, 2/2 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 9,10

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 9,10

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. IV Lack of unity of invention**

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1. ☒ In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☒ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
  - ☐ not complied with for the following reasons:
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-8 .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	3-8
	No: Claims	1,2
Inventive step (IS)	Yes: Claims	3-8
	No: Claims	1,2
Industrial applicability (IA)	Yes: Claims	1-8
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Re Item IV.**

- 1 The separate inventions/groups of inventions are:  
Claims 1,2-8: A tracheostomy device with a seal sealing above the opening into the trachea (problem: the secretions produced in the upper part of the trachea tend to collect on the inflated cuff which provides a site for the accumulation of bacteria).  
Claims 1,9,10: A tracheostomy device with an internal retainer in the form of a displaceable member (problem: to secure the tube to the neck without the use of a strap).

- 2 They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

- 2.1 The document US-A-3889688 cited in the search report discloses a tracheostomy device comprising essentially:
- a tubular member,
  - an external retainer,
  - an internal retainer.

Over this prior art, no special technical feature (in the meaning of Rule 13.2 PCT) remains in claim 1 of the application.

- 2.2 Over this prior art, the potential special technical features (in the meaning of Rule 13.2 of the PCT) in the dependent claims are:

Claims 1, 2-8: a seal for sealing the trachea above the opening,

Claims 1, 9,10: internal retainer in the form of a displaceable member.

- 2.3 Accordingly, it appears that a posteriori, the above listed claims do not satisfy the requirement of unity of invention.

- 2.4 Furthermore, it is pointed out that also when considering the effects associated with

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the different groups of claims, no single general inventive concept exists between said different groups. Since there exists no other common special technical feature within the meaning of Rule 13.2 PCT, no technical relationship between the different groups of claims can be seen.

**Re Item V.**

- 3 The following document is referred to in this communication:  
D1 : US 4 278 081 A (JONES JAMES W) 14 July 1981 (1981-07-14)

**4 INDEPENDENT CLAIM 1**

- 4.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.  
Document D1 (see column 4, line 52 - column 5, line 47, figures 1,2) discloses (the references in parenthesis applying to this document):  
A tracheostomy device including a tubular member (20) adapted to provide a gas passage into the trachea (14) through an opening in neck tissues and an external retainer (21) for retaining the tubular member with the external surface of the neck adjacent the opening, wherein the patient end (24) of the tubular member (20) terminates adjacent the internal end of the opening, and that the device includes an internal retainer (30) for retaining the tubular member with the internal surface of the trachea adjacent the opening.

**5 DEPENDENT CLAIM 2**

Dependent claims 2 and 5 to 8 when dependent on claim 2 does not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT).

- 5.1 In particular, the features of claim 2 are disclosed in combination with the features of



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claim 1 in D1, see column 4, line 52 - column 5, line 47, figures 1,2, and therefore their subject matter is not novel.

- 5.2 In particular, the features of claims 5 to 8 when dependent on claim 2 are merely one of the straightforward possibility from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

**6 DEPENDENT CLAIM 3**

Dependent claim 3 as far as it is dependent on claim 2, fulfills the requirements of Article 33(2) to (3) PCT.

- 6.1 Claim 3 differs from D1 in "the seal includes a fluid passage opening at one end above the seal and extending out of the trachea via the opening".  
In view of this difference, the subject matter of claim 3 is new and therefore meet the requirements of Article 33(2) PCT.
- 6.2 The problem to be solved by the present invention according to claim 3 may therefore regarded as "to reduce the accumulation of bacteria"
- 6.3 Claim 3 is neither known nor rendered obvious by, the available prior art. The advantage of the present invention is to "reduce the secretion build up on the inside of the tube by evacuating it through a fluid passage". In the prior art, there is no "evacuating fluid passage". Therefore it is not obvious to provide an evacuating passage from the "obturator".  
Therefore the subject matter of claim 3 meets the requirements of Article 33(3) PCT.
- 6.4 Claims 4 to 8 when dependent on claim 3 refer to preferable embodiments which fulfill the requirements of Article 33(2) and (3) PCT.
- 7 The tracheostomy device of claim 1 is industrially applicable, and therefore the requirements of Article 33(4) PCT are met.

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- 7.1 Dependent claims 2-8 are preferred embodiments of claim 1. In view of that, claims 2-8 meet the requirements of Article 33(4) PCT.

**Re Item VII.**

- 8 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

**Re Item VIII.**

- 9 The subject matter of claim 1 is unclear (article & PCT) since it is defined (see "patient end") in relation to features not forming part of the claim (see "opening"). They are only "suitable for". In particular, the feature of claim 1 "a tubular member adapted to provide a gas passage into the trachea through an opening in neck tissues" is not defined. The same applies for the feature "an external retainer for retaining the tubular member with the external surface of the neck adjacent the opening", and for the feature "an internal retainer for retaining the tubular member with the internal surface of the trachea adjacent the opening".